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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/780,638  | 02/19/2004  | Ming Bo Wang         | 021565-156                  | 2125             |
| 21839 7590 01/25/2007<br>BUCHANAN, INGERSOLL & ROONEY PC<br>POST OFFICE BOX 1404<br>ALEXANDRIA, VA 22313-1404 |             |                      | EXAMINER<br>KALLIS, RUSSELL |                  |
|   |             |                      | ART UNIT<br>1638            | PAPER NUMBER     |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE               |                  |
| 3 MONTHS  |             | 01/25/2007           | PAPER                       |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/780,638

Applicant(s)

WANG ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/09/06; 11/07/06</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Groups B and III in the reply filed on 11/07/2006 is acknowledged. The traversal is on the ground(s) that the recited Pol III promoters share common chemical, structural, and functional features. This is not found persuasive because Applicant's argument that the groups are related simply because they are nucleic acids does not address features held in common to that group alone, that would distinguish it from other nucleic acids. Further, Applicant's arguments that recognizing Pol III promoters is a sufficiently distinguishing feature to establish an election of species, ignores the fact that in the art it is recognized that promoters encompassing different primary sequences, having different tissue specific expression, developmental regulation, or constitutive expression as well as promoters that respond to various physiological conditions and environmental stimuli are properly restricted, yet they all bind a common polymerase and are nucleic acids. With respect to the "Examination of Patent Applications Containing Nucleotide Sequences" from the (Official Gazette 1192 OG 68 Nov. 19, 1996) and the MPEP, Applicant's remarks are not found persuasive because sequences of SEQ ID NO: 1-6 are unique DNA compositions requiring a different search. The prior indication, in 1996, that up to ten sequences were permissible was meant to apply to EST sequences, rather than promoters or coding sequences. Furthermore, since 1996 resources at the Patent office have changed, and the examination and search of more than one sequence would pose an undue burden. Finally, the MPEP also recites in 803.04 that "up to ten independent and distinct inventions can be examined", and thus one sequence constitutes "up to ten".

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The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are pending and examined.

### ***Sequence Listing***

The description of SEQ ID NO: 5 and 6 on pages 4-5 of the sequence listing do not match the description of SEQ ID NO: 5 and 6 presented on pages 17-18 of the specification.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

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USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation “comprising about 19 contiguous nucleotide sequences” in part 1, and the claim also recites “capable of forming a double stranded RNA of about 19 to about 200 nucleotides in length” which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wesley S. *et al.* The Plant Journal, 2001; Vol. 27, no. 6; pp. 581-590 in view of Yukawa Y. *et al.* Plant Molecular Biology, 2002; Vol. 50, pp. 713-723 and Applicant's specification.

The claims are broadly drawn to a method of reducing gene expression in a plant cell by trnaformation with a type 3 pol-III promoter that transcribes a sense and corresponding antisense message comprising about 19 contiguous nucleotide sequences of any gene of interest having about 90 to 100% sequence identity.

Wesley teaches post translational silencing of plant genes using ihpRNA as small as 98 base pairs and that dsRNA of at least 21 nucleotides in length have been associated with plants having post translational gene silencing (page 587 Table 1 and page 588 column 2 lines 18-30).

Wesley does not teach using a Pol-III type 3 promoter.

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Yukawa teaches using 7SL type 3 pol-III promoter and Pol-III type 3 promoters in general in plant cells because they are recognized in the art as strong promoters for driving gene inhibition in plants (see Abstract; page 714 column 1 2<sup>nd</sup> full paragraph; and the full discussion).

Applicant specification teaches that Pol-III promoters of U3, U6 and 7SL were known in the art; especially SEQ ID NO: 3 from *Arabidopsis* (GenBank X52629).

It would have been obvious at the time of invention to modify the invention of Wesley to include the Pol-III promoter of Yukawa or those available in the art. One of ordinary skill in the art would have been motivated by the knowledge common in the art that dsRNA as small as 21 nucleotides and Pol-III type 3 promoters are valuable materials for genetic engineering of gene expression reduction as taught by Wesley and that one of ordinary skill in the art would have appreciated that Pol-III type promoters are strongly expressed in all tissues and that Pol-III promoters were available in the art as taught by Applicant's specification, and that one would have had a reasonable expectation of success of reducing gene expression given the success of Wesley using dsRNA and of Pol-III promoters expressing in transformed plants and plant cells given the success of Yukawa; and wherein using a dsRNA of 19 or 20 nucleotides in length is an obvious design step given the lack of criticality.

All claims are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Russell Kallis Ph.D.  
January 20, 2007

RUSSELL P. KALLIS, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Russell Kallis". The signature is written in a cursive, flowing style.